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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/641,012	08/16/2000	William Russell Kanz	PA036	6843

7590

10/04/2004

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EXAMINER

BIANCO, PATRICIA

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 10/04/2004

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/641,012

Applicant(s)

KANZ ET AL.

Examiner

Patricia M Bianco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 15.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☒ Other: Final Rejection.

DETAILED ACTION

Response to Amendment

Applicant amended claims 1, 5 & 13 and cancelled claims 2 & 14-17. As a result of the amendments, claims 1 & 3-13 remain pending.

Response to Arguments

Applicant's arguments with respect to claims 1 & 3-13 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of

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35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-11, & 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reich et al. (4,135,253) in view of Runge (5,688,245). Reich et al. (hereafter Reich) discloses a centrifugal blood pump (10) having a main inlet port (12), a main outlet port (14) and supplemental ports, inflow (30) and outflow (32), all operably connected to the blood pump. Reich discloses that the blood pump is used in a method of pumping blood from a heart into and out of the main ports. Reich also discloses that the blood flows into the pump via a cannula and out via a tube. It is inherent that the ports will be connected to flow tubing, i.e. catheters or cannulae, that are capable of being adapted to supply blood to a vein or artery or adapted to be positioned within an artery or the aorta.

Reich et al. discloses the invention substantially as claimed, however, fails to disclose specifically that the supplemental port have a valve and that the conduit coupled to the supplemental outflow port has a structure sized and configured to occlude a blood vessel. Runge discloses a bypass system including a blood pump and tubing or cannula in communication with the pump. Runge further teaches that inflow and outflow conduits may include a valve for control of fluid therethrough. Runge also discloses balloons on the cannula for occluding a vessel. It would have been obvious at the time of the invention to modify the system of Reich by including valves in at least the tubing in communication with the supplemental port since it was well known at the time to

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use valved tubing to control fluid into and out of blood pumps and bypass systems as well as including a balloon on the cannula for blocking the vessel said cannula is disposed in, since it is well known to use balloons in blood pumping systems.

Claim 1, 3-11, & 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Izraelev (5,685,700) in view of Runge (5,688,245). Izraelev discloses a blood pump (10) having a pair of inlet ports (16 & 17) and a pair of outlet ports (18 & 19). Thus, the supplemental port may be either an inflow or outflow port. Izraelev discloses that the pump may have the outlets coupled to the aorta. With respect to the ports connected to catheters and/or cannulae, it is inherent that the ports will be connected to flow tubing, i.e. catheters or cannulae, such that blood is delivered from the heart to the pump and that these catheters and/or cannula are capable of being adapted to supply blood to a vein or artery or adapted to be positioned within an artery or the aorta. Izraelev discloses the invention substantially as claimed, however, fails to disclose specifically that the supplemental port has a valve and that the conduit coupled to the supplemental outflow port has a structure sized and configured to occlude a blood vessel.

Runge discloses a bypass system including a blood pump and tubing or cannula in communication with the pump. Runge further teaches that inflow and outflow conduits may include a valve for control of fluid therethrough. Runge also discloses balloons on the cannula for occluding a vessel. It would have been obvious at the time of the invention to modify the system of Izraelev by

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including valves in at least the tubing in communication with the supplemental port since it was well known at the time to use valved tubing to control fluid into and out of blood pumps and bypass systems as well as including a balloon on the cannula for blocking the vessel said cannula is disposed in, since it is well known to use balloons in blood pumping systems.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reich et al. & Runge in further view of Afzal et al. (6,387,323). Reich & Runge discloses the invention substantially as claimed, see rejection supra. Reich & Runge, however, fails to disclose specifically that the blood pump is connected to an oxygenator. Afzal et al. (hereafter Afzal) discloses a system having a blood pump in communication with a blood oxygenator to provide blood oxygenation while a patient is on cardiopulmonary bypass. It would have been obvious at the time of the invention to couple the pump of Reich to a blood oxygenator since it was well known at the time for cardiopulmonary bypass systems to have a pump coupled to an oxygenator to supply deoxygenated blood to the oxygenator for oxygenation and subsequently delivering the oxygenated blood back to the patient while the heart is on bypass to prevent the vital organs of the patient to become ischemic thereby preventing any damage during the bypass procedure.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Izraelev & Runge in further view of Afzal et al.(6,387,323). Izraelev & Runge discloses the invention substantially as claimed, see rejection supra. Izraelev &

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Runge, however, fails to disclose specifically that the blood pump is connected to an oxygenator. Afzal et al. (hereafter Afzal) discloses a system having a blood pump in communication with a blood oxygenator to provide blood oxygenation while a patient is on cardiopulmonary bypass. It would have been obvious at the time of the invention to couple the pump of Izraelev to a blood oxygenator since it was well known at the time for cardiopulmonary bypass systems to have a pump coupled to an oxygenator to supply deoxygenated blood to the oxygenator for oxygenation and subsequently delivering the oxygenated blood back to the patient while the heart is on bypass to prevent the vital organs of the patient to become ischemic thereby preventing any damage during the bypass procedure.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will

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the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 30th, 2004


PATRICIA BIANCO
PRIMARY EXAMINER

Patricia M Bianco
Primary Examiner
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